

1 Zonisamide Tablets

2 ズニサミド錠

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4 Zonisamide Tablets contain not less than 95.0% and not
5 more than 105.0% of the labeled amount of zonisamide
6 ($C_8H_8N_2O_3S$: 212.23).

7 **Method of preparation** Prepare as directed under Tablets, with
8 Zonisamide.

9 **Identification** To 5 mL of the sample solution obtained in the
10 Assay add 5 mL of methanol. Determine the absorption spectrum
11 of this solution as directed under Ultraviolet-visible Spectropho-
12 tometry <2.24>: it exhibits maxima between 237 nm and 241 nm,
13 between 243 nm and 247 nm, and between 282 nm and 286 nm.

14 **Uniformity of dosage unit** <6.02> Perform the Mass variation
15 test, or the Content uniformity test according to the following
16 method: it meets the requirement.

17 To 1 tablet of Zonisamide Tablets add $V/25$ mL of water, disin-
18 tegrate completely by sonicating, add $7V/10$ mL of methanol, and
19 shake for 15 minutes. Add methanol to make exactly V mL so that
20 each mL contains about 0.5 mg of zonisamide ($C_8H_8N_2O_3S$). Cen-
21 trifuge this solution, pipet 3 mL of the supernatant liquid, add
22 methanol to make exactly 50 mL, and use this solution as the sam-
23 ple solution. Then, proceed as directed in the Assay.

$$24 \quad \text{Amount (mg) of zonisamide (C}_8\text{H}_8\text{N}_2\text{O}_3\text{S)}$$

$$25 \quad = M_S \times A_T / A_S \times V / 75$$

26 M_S : Amount (mg) of Zonisamide RS taken

27 **Dissolution** <6.10> When the test is performed at 50 revolutions
28 per minute according to the Paddle method, using 900 mL of water
29 as the dissolution medium, the dissolution rate in 45 minutes of
30 25-mg tablet is not less than 75%, and those in 10 minutes and 45
31 minutes of 100-mg tablet are not more than 65% and not less than
32 70%, respectively.

33 Start the test with 1 tablet of Zonisamide Tablets, and withdraw
34 exactly 20 mL of the medium at the specified minutes after starting
35 the test. In the case of 100-mg tablets, supply exactly 20 mL of
36 water warmed to $37 \pm 0.5^\circ\text{C}$ immediately after withdrawing of the
37 medium every time. Filter these media through a membrane filter
38 with a pore size not exceeding $0.45 \mu\text{m}$. Discard the first 10 mL
39 of the filtrate, pipet V mL of the subsequent filtrate, add water to
40 make exactly V' mL so that each mL contains about $22 \mu\text{g}$ of zo-
41 nisamide ($C_8H_8N_2O_3S$), and use this solution as the sample solu-
42 tion. Separately, weigh accurately about 22 mg of Zonisamide RS,
43 previously dried at 105°C for 3 hours, and dissolve in water to
44 make exactly 100 mL. Pipet 5 mL of this solution, add water to
45 make exactly 50 mL, and use this solution as the standard solution.
46 Determine the absorbances, $A_{T(n)}$ and A_S , of the sample solution
47 and standard solution at 285 nm as directed under Ultraviolet-vis-
48 ible Spectrophotometry <2.24>.

49 Dissolution rate (%) with respect to the labeled amount of zonis-
50 amide ($C_8H_8N_2O_3S$) on the n th medium withdrawing ($n = 1, 2$)

$$51 \quad = M_S \times \left\{ \frac{A_{T(n)}}{A_S} + \sum_{i=1}^{n-1} \left(\frac{A_{T(i)}}{A_S} \times \frac{1}{45} \right) \right\} \times \frac{V'}{V} \times \frac{1}{C} \times 90$$

52 M_S : Amount (mg) of Zonisamide RS taken

53 C : Labeled amount (mg) of zonisamide ($C_8H_8N_2O_3S$) in 1 tablet

54 **Assay** Weigh accurately the mass of not less than 20 Zonisam-
55 ide Tablets, and powder. Weigh accurately a portion of the powder,
56 equivalent to about 75 mg of zonisamide ($C_8H_8N_2O_3S$), and mois-
57 ten with 2 mL of water. Add 70 mL of methanol, shake for 15
58 minutes, and add methanol to make exactly 100 mL. Centrifuge
59 this solution, pipet 2 mL of the supernatant liquid, add methanol
60 to make exactly 50 mL, and use this solution as the sample solu-
61 tion. Separately, weigh accurately about 38 mg of Zonisamide RS,
62 previously dried at 105°C for 3 hours, dissolve in 1 mL of water
63 and methanol to make exactly 50 mL. Pipet 2 mL of this solution,
64 add methanol to make exactly 50 mL, and use this solution as the
65 standard solution. Determine the absorbances, A_T and A_S , of the
66 sample solution and standard solution at 284 nm as directed under
67 Ultraviolet-visible Spectrophotometry <2.24>.

$$68 \quad \text{Amount (mg) of zonisamide (C}_8\text{H}_8\text{N}_2\text{O}_3\text{S)}$$

$$69 \quad = M_S \times A_T / A_S \times 2$$

70 M_S : Amount (mg) of Zonisamide RS taken

71 **Containers and storage** Containers— Tight containers.

72 **Add the following to 9.01 Reference Stand-**
73 **ards (1) :**

74 **Zonisamide RS**

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